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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,128	12/15/2003	Michael John Rutter	CHM-010	5727

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MASON, OH 45040

EXAMINER

PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/737,128	Applicant(s) RUTTER, MICHAEL JOHN	
	Examiner Nihir Patel	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17-25 is/are allowed.
- 6) ☒ Claim(s) 1-7, 13 and 15 is/are rejected.
- 7) ☒ Claim(s) 8-12, 14 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on January 12th, 2006 have been fully considered but they are not persuasive.
2. **As to claims 1 and 3-7 being rejected under 35 USC 102(b)**, the applicant argues that Inglis does not disclose a tracheostomy endotracheal tube that is a single tube. It has been held "that the use of a one piece construction instead of the structure disclosed in Inglis would be merely a matter of obvious engineering choice." *In re Larson*, 340 F.2d 965, 144 USPQ 347, 349 (CCPA 1965). The applicant also argues that Inglis does not disclose an obtuse angle bend in its tracheal tube assembly. The examiner disagrees. Figure 1 in Inglis does disclose an obtuse angle bend in its tracheal tube assembly.
3. **As to claims 1, 3-11, 15, 17 and 26 being rejected under 35 USC 103(a)**, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It would have been obvious to use the accordion pleats 10 between the intermediate section and the distal section can be used to adjust the length of the distal section and the intermediate section to any desired ratios. Since the applicant's specification has not establish any criticality in reference to the ratios, it is considered a matter of design choice and therefore it would be

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obvious to one in the ordinary skill of the art that through mere routine experimentation could arrive at the claimed length ratios, because one of ordinary skill in the art would have known that different ratios are required for different user's and in different procedures being performed (pediatric, infant, adolescent, adult, elderly, thin, obese, patients) and such users would require different ratio lengths of the sections of the tracheotomy tube in order for the tube to be used in different and with different users.

4. **As to claims 2, 12, 18-20 and 23-25 being rejected under 35 USC 103(a)**, in response to applicant's argument that Nye (US 5,590,647) is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, it would have been obvious to modify Beck's invention by providing a flexible tube that is made of a thermoplastic material preformed to the shape described as taught by Nye in order to make it easier for the tube to be placed in a desired position so that it will not be dislodged from the patient and allow OR staff to provide any care needed.

5. **As to claims 13, 14, 16, 21 and 22 being rejected under 35 USC 103(a)**, In response to applicant's argument that Joseph (US 5,582,167) is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, it would have been obvious to modify Beck's

invention by providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being other wise imperforate as taught by Joseph in order to make it easier to deliver oxygen or any other medication.

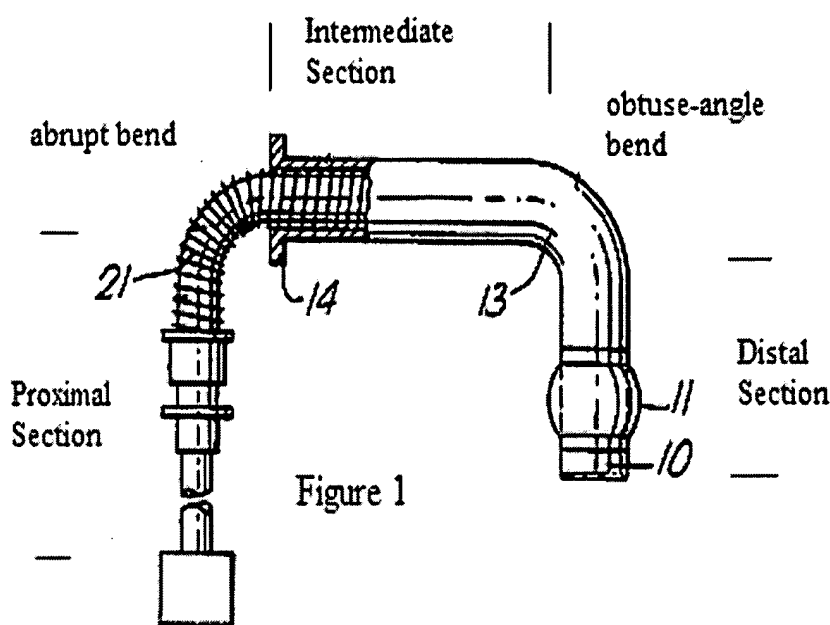
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **1 and 3 through 7** are rejected under 35 U.S.C. 102(b) as being anticipated by Inglis et al. (US 5,386,826). **Referring to claim 1**, Inglis discloses an apparatus that comprises a short distal section of the tubing **10 (see figure 1 below)**; and intermediate section of the tubing (**see figure 1 below**); a pre-formed obtuse angle bend in the tube between the distal and intermediate sections (**see figure 1 below**); an elongated proximal section of the tubing; a pre formed abrupt bend in the tube between the intermediate and proximal sections (**see figure 1 below**); and an inflatable cuff **11 (see figure 1 below)** integrated into the distal section of the tubing.



Referring to claim 3, Inglis discloses an apparatus wherein the abrupt bend interconnects the proximal section and the intermediate section along the length of the tube at an angle of from about 80 to about 95 degrees (see figure 1 above).

Referring to claim 4, Inglis discloses an apparatus wherein the abrupt bend interconnects the proximal section and the intermediate section along the length of the tube at approximately a right angle (see figure 1 above).

Referring to claim 5, Inglis discloses an apparatus wherein the distal section, intermediate section and the proximal section extend the same general plane (see figure 1 above).

Referring to claims 6 and 7, Inglis discloses an apparatus wherein the distal section, intermediate section and the proximal section are substantially rectilinear in formation (**see figure 1 above**).

Referring to claim 15, Inglis discloses an apparatus wherein the inflatable cuff securely locates the distal section in a patient's trachea and substantially prevents leakage of air back out the patient's mouth during positive pressure ventilation (**see figure 1 above**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **13** is rejected under 35 U.S.C. 103(a) as being unpatentable over Inglis et al. (US 5,386,826) in view of Joseph (US 5,582,167). **Referring to claims 13**, Inglis discloses the applicant's invention as claimed with the exception of providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise

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imperforate. Joseph discloses methods and apparatus for reducing tracheal infection using subglottic irrigation, drainage and servo-regulation of endotracheal tube cuff pressure that does provide a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate. Therefore it would have been obvious to modify Inglis's invention by providing a distal section that has a beveled terminal end with at least one port opening adjacent thereto, the tube being otherwise imperforate as taught by Joseph in order to make it easier to deliver oxygen or any other medication.

Claims **17-25** are allowed.

Claims **8-12, 14 and 16** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-4791.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nihir Patel
Art Unit 3743



Henry Bennett
Supervisory Patent Examiner
Group 3700